

Remarks

Claims pending in this application are claims 1-22. The Examiner has set forth twelve inventions in the outstanding office communication. Part of the reasoning for such restriction, as set forth on page 5 of the outstanding office communication, is "because the inventions are drawn to distinct compositions and materially different methods." Further, it is stated on page 5, "Animals having different genetic modifications constitute distinct inventions. The animals are not obvious variants, one over the other."

In order to be responsive, election of group I, is hereby made with traverse. Reconsideration of the restriction requirement is respectfully requested in view of the following.

Applicants traverse in part on the grounds that joinder of the method invention of groups I-IV identified in the Restriction Requirement places no undue burden on the Patent Office, as the field of search for each of the inventions is similar. The method of the invention regards somatic gene transfer to a specific area of the brain of an organism to model neurodegenerative diseases. The method has been proven for a number of genes. The novelty and non-obviousness of the method should stand independently of assertions of distinct inventions comprised of different genetically modified organisms. Also, the method of the present invention, and the animals that result from such method with different genes somatically transferred, should not be held to the same standard as a transgenic organism. In the latter, every cell of the organism has a distinct genetic make-up as a result, typically, of germ line genetic manipulation. Here, the method is the key in that it focuses a desired gene to a very limited area of the brain, leading to a greater understanding of neurodegenerative disease processes and treatments.

Also, when certain genes for aberrant proteins are administered in combination, greater effects are detected. The scope of such a method should not be limited by a relationship to alleged distinctness of animals that result from such method.

Also, searches required for these "separate inventions" are coextensive. This is, in part, because the base independent claim 1 is to a method of somatic gene transfer into specific sections of a brain of a model animal. This method is and can be used for administering various combinations of genes coding proteins that alter brain histology and function in ways that model neurodegenerative diseases. The Examiner is referred to the application, page 2, lines 24-29 (where APP, PS1, IL6 and Tau genes were administered in one treatment); behavioral effects of rats receiving this combined vector treatment is shown in Figure 5. See also page 12, line 28, to page 13, line 2, and Example 7 in its entirety. Given this disclosure and results, the Patent Office's assertion of distinctness of these inventions appears difficult to reconcile with the fact that the vectors of different genes can and are combined in one treatment, resulting in a desired effect with regard to development of a model of neurodegenerative disease.

Also, a search for methods of somatic gene transfer to develop a model for neurodegenerative diseases will reveal all relevant references for methods for somatic gene transfer of tau, alpha-synuclein, APP, and presenelin-1.

Also, invention V is to claims 9 and 10. Claim 10 depends on claim 1, and add specific limitations to claim 1. Contrary to the statement in the Office Communication, claim 10 does not depend on the claim that regards "a method for identifying a combination of genes relevant to human pathology." The inclusion of claim 10 in Invention V is improper and should be corrected.

Finally, Applicants point out that restriction practice under 35 USC § 121 is discretionary, not mandatory, and that efficiency and economy considerations would be far better served by concurrent examination of all invention groups. Therefore, Applicants request the reconsideration of the outstanding restriction requirement and that examination of all invention groups ensue.

In view of the foregoing remarks, it is respectfully urged that all grounds for restriction have been addressed and overcome herein. Reconsideration and withdrawal of all grounds for restriction is therefore respectfully requested.

Applicant invites the Examiner to call the undersigned if clarification is needed on any aspect of this response, or if the examiner believes that any valid basis remains for

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maintaining the traversed restriction of the claims presented in this application after entrance and consideration of the remarks presented herein.

Respectfully submitted,



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